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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/684,759	10/14/2003	Li Wang	P0011118.00/LG10126	3360

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EXAMINER	
ALTER, ALYSSA MARGO	

ART UNIT	PAPER NUMBER
3762	

NOTIFICATION DATE	DELIVERY MODE
09/10/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

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Office Action Summary	Application No.	Applicant(s)	
	10/684,759	WANG ET AL.	
	Examiner	Art Unit	
	Alyssa M. Alter	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *June 10, 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *80-82,84-87 and 96* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) *80-82,84-87 and 96-103* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *14 October 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments filed June 10, 2010 have been fully considered but they are not persuasive. The Applicant admits "it is not disputed that the general concept of adding a lead impedance checking function to the Combs'861 device is obvious. Lead impedance testing is a well known function of cardiac pacemakers and the general notion of adding it to any pacemaker, in some way or other, is acknowledged to be obvious" (page 11). However the Applicant argues that the claims "specifically require that the same measured impedances are used to both measure fluid content and to monitor lead integrity" and that "adding the impedance measurement function of Scheulke to Combs '681 does not produce or suggest this result". The examiner respectfully disagrees. The Applicant contents that it would not be obvious to employ the lead integrity measuring system of Schuelke et al. to the leads in Combs since this would result in two separate lead measurements.

However, Schuelke et al. discloses "the lead integrity check may also be undertaken during delivery of a pacing pulse" (col 3, lines 22-23). Therefore, the system does not require the separate measurements, but can be used at the same time. In addition, "impedance trend suggesting an impending failure that may be monitored more closely or may result in replacement of the lead or re-positioning of the lead electrode" (col. 3, lines 303-35). Therefore, Schuelke et al. discloses the monitoring of the impedance data taken during a delivery pulse, as well as the trending to monitor the impending failure of a lead.

As a result, the modified Combs et al. further employs "the measured impedances to assess the integrity of the leads". Therefore the claims remain rejected under Combs et al. in view of Schuelke et al. as previously presented.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

1. Claims 80-82, 84-87 and 96-103 are rejected under 35 U.S.C. 103(a) as being unpatentable over Combs et al. (US 5,957,861) in view of Schuelke et al. (US 5,755,742). Combs et al. discloses a system to produce impedance measurements in a subcutaneous portion of the body with at least two electrodes. "Also depending on the location of the electrodes used for measurement, it is wise to consider synchronization to the heart beat cycle and the respiratory cycles or the variation in measurement resulting from measuring at inconsistent times within these cycles may cause insurmountable difficulties in extracting useful signal from the impedance changes created by these cycles. (col. 6, lines 51-57). Therefore, since the impedance measurements are synchronized with the cardiac cycle, they are responsive to a cardiac event.

"The determination of pulmonary edema or local edema will be based upon comparison of long term average impedance value compared to the short term average

value" (col. 9, lines 64-67). "A determination of how severe the disease is by how quickly the edema progresses (i.e. if the change was seen over the course of two weeks, versus one day) becomes a measure that has value to the patient and physician and can be a stored value kept in a memory circuit by a device made in keeping with this invention"(col. 9, lines 53-59). Furthermore, "Long term average preferably represents the number of days (in the most preferred embodiment three to thirty) while the short term average represents the number of hours (preferably one to forty-eight)"(col. 10, lines 14-18).

Combs et al. discloses the claimed invention except for assessing the integrity of the leads. Schuelke et al. discloses a lead integrity measuring system that measured impedance values to determine lead integrity failures. It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the system of Combs et al. to include a lead integrity measuring system as taught by Schuelke et al. in order to provide the predictable results of ensuring the leads are in proper working order. Furthermore, checking the integrity of the leads would ensuring the sensed values are accurate.

As to claims 86-87 and 102-103, Schuelke et al. discloses a device with three leads where each lead has an electrode. Wherein the third electrode provides a cross check of measured impedance values. "Testing current and voltage lead integrity of at least one of the leads comprising the steps of and means for: selecting one of the at least three leads as a lead under test, a force lead and a measure lead; coupling the terminal of the lead under test to a fixed potential; driving an excitation voltage pulse in

an excitation path including the terminal of the selected force lead, the force lead electrode/tissue interface, the lead under test electrode/tissue interface and the lead under test; measuring the excitation current value of the excitation voltage pulse delivered in the excitation path through the lead under test; and measuring an induced voltage in a measure path including the terminal of the selected measure lead, the measure lead electrode/tissue interface, the lead under test electrode/tissue interface and the lead under test". The lead impedance of the lead under test is derived from the measured excitation current value and the induced voltage value. In order to test the lead integrity of the remaining leads, the selection of the lead under test, the force lead and the measure lead are changed, and the test is repeated"(col. 4, lines 46-65). Therefore, the modified Combs et al. discloses performing a cross-check of measured impedance values with a third electrode.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to telephone number is (571)272-4939. The examiner can normally be reached on M-F 8am to 4pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Niketa Patel, can be reached on 571-272-4156. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Niketa I. Patel/
Supervisory Patent Examiner, Art Unit 3762

/Alyssa M Alter/
Examiner
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